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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,378	01/19/2001	Peter R. Rhode	48002-DIV (1758)	8910

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT PAPER NUMBER

1644

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 09/766,378	<b>Applicant(s)</b> RHODE ET AL.	
	<b>Examiner</b> F. Pierre VanderVegt	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-29, 38-43, 45 and 47-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-29, 39, 40, 45 and 47-49 is/are rejected.
- 7) ☒ Claim(s) 38 and 41-43 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |



Art Unit: 1644

### DETAILED ACTION

This application is a divisional of U.S. Application Serial Number 08/960,190.

Claims 1-24, 30-37, 44 and 46 have been canceled.

Claims 25-29, 38-43, 45 and 47-49 are currently pending.

In view of Applicant's amendments filed August 5, 2005 and November 29, 2004 no outstanding grounds of rejection are maintained.

Due to re-evaluation of the terms "at least one" and "ligand binding molecule" in the claims, the following represent NEW grounds of rejection and necessitate this Office Action being made NON-FINAL.

#### *Double Patenting*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 25-29, 39, 40, 45, and 47-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17 and 24 of U.S. Patent No. 5,869,270 to Rhode et al (of record). Although the conflicting claims are not identical, they are not patentably distinct from each other when "A represents at least one empty sc-MHC class II molecule" [recited in claims 25, 26, 28, 29, 45 and 47-49] and "D represents at least one ligand binding molecule" because claim 17 of the '270 patent is drawn to multimeric (or polyspecific) complexes of single chain MHC class II molecules. Claim 17 of the '270 patent, by way of its base claim, recites that the MHC class II molecule is composed of a class II beta chain and a class II alpha chain linked in sequence and does not recite that a peptide antigen is either attached or associated with the MHC molecule. Accordingly, the claim reads upon "empty" MHC molecules. Claim 17 read in light of 24 of the '270 patent recites an embodiment that the presenting peptide is covalently linked to the MHC molecule. The

Art Unit: 1644

recitation in the instant claims that "A represents at least one" MHC molecule is reasonably interpreted as including two MHC molecules. In addition, the recitation "D represents at least one ligand binding molecule" reasonably reads upon an MHC molecule as well because an MHC molecule binds presenting peptides as a receptor would bind a ligand. While claim 17 of the '270 patent does not specifically recite "joining molecule," the claim is broadly drawn to read upon any multivalent MHC class II complex comprising two or more "linked" single chain MHC class II molecules, and the purpose of the joining molecules in the instant claims is to link the sc-MHC class II molecules. Accordingly, the instantly claimed polyspecific MHC complex when "A represents at least one empty sc-MHC class II molecule" and "D represents at least one ligand binding molecule" constitutes a species of the multivalent MHC complex of claim 17 or of claims 17 and 24 of the '270 patent.

#### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 26, 29, 47 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26, 29, 47 and 49 are ambiguous and unclear in the recitation of "B is a joining molecule." In the case where the formula of the construct is B-A-C or A-C-B, the "B" element does not join A or C to anything else.

#### *Allowable Subject Matter*

5. Claims 38 and 41-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### *Conclusion*

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00 and Alternate Fridays 6:30-3:00.

Art Unit: 1644

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. *PV*  
Patent Examiner  
July 14, 2005

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT ~~102~~ 1644